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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-------------------------|-------------|----------------------|-------------------------|------------------|
| 09/828,624 | 04/03/2001 | Lorraine D. Butlin | IMIN.P-033 | 8891 |
| 21121 | 7590 | 04/21/2004 | EXAMINER | |
| OPPEDAHL AND LARSON LLP | | | PORTNER, VIRGINIA ALLEN | |
| P O BOX 5068 | | | | |
| DILLON, CO 80435-5068 | | | ART UNIT | PAPER NUMBER |
| | | | 1645 | |

DATE MAILED: 04/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------|------------------------|---------------------|
| Advisory Action | Application No. | Applicant(s) |
| | 09/828,624 | BUTLIN ET AL. |
| | Examiner | Art Unit |
| | Ginny Portner | 1645 |

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) The period for reply expires ____ months from the mailing date of the final rejection.
- b) The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. A Notice of Appeal was filed on 12/15/2003. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. The proposed amendment(s) will not be entered because:
 - (a) they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) they raise the issue of new matter (see Note below);
 - (c) they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: see attached.

3. Applicant's reply has overcome the following rejection(s): ____.
4. Newly proposed or amended claim(s) ____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. The a) affidavit, b) exhibit, or c) request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. For purposes of Appeal, the proposed amendment(s) a) will not be entered or b) will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: 15-16.

Claim(s) objected to: 18-35, 18-39 & 40/4

Claim(s) rejected: 18-35

Claim(s) withdrawn from consideration: ____.

8. The drawing correction filed on ____ is a) approved or b) disapproved by the Examiner.

9. Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). ____.

10. Other: ____

Continuation of 5. does NOT place the application in condition for allowance because: the remarks are directed to a combination of claim limitations not entered After Final.

For at least the following reasons, the Amendment After Final is not being entered:

1. The combination of the claim limitations of claim 18 and 29, results in a lack of clarity as to what sample is being analyzed at an interval of “at least one week” to further determine the menopausal statue of the female.

The definition of the term “contemporaneous” at page 8, lines 12-27 defines this term to include: Samples that have been sub-divided into multiple portions obtained from the same individual, or more than one sample obtained from the same individual on the same day, within a couple of hours of each other.

Claim 29 depends from claim 18(independent claim), and recites “further comprising the step of repeating the two contemporaneous assay after an interval of at least one week to determine is menopausal status of the human female individual is changing”,

With the proposed amendment to recite “the same sample obtained from step a”, claim 29 is unclear as to what sample is being analyzed that would meet the definition of contemporaneous samples. Claim 29 appears to be analyzing the “same sample” set forth in claim 18, but the sample of claim 18 that is “at least one week” old, would not meet the definition of “contemporaneous set forth in the instant specification.

The newly proposed combination of claim limitations set forth in claim 18 raises a new issue, as no changes could be determined on the same sample at least one week later, and a sample at least one week old does not meet the definition of a contemporaneous sample as defined in the instant specification.

2. Claim 31 (an assay device) is proposed to be amended to comprise “means for combining signals produced by the first and second gonadotropin-responsive signal producing means; changed from “means for combining the signals for the first and second gonadotropin-responsive signal producing means.

The currently pending claimed “means” reads on a bottle, test tube, assay device solid phase nitrocellulose strip; while the newly proposed claim limitations also reads on a light reading device that combines the signals to determine a level of emission which results in “combining the signals. The proposed claim limitations changes/modifies the scope of the claimed invention, and raises a new issue After Final.

3. Additionally, Claim 33 which currently recites the phrase “wherein the first and second gonadotropin-responsive signal producing means produce a signal” is proposed to recite “means” each “produce a signal”, thus requiring two signal producing means, rather than “a signal” as currently recited in pending claim 33. The proposed claim limitations changes/modifies the scope of the claimed invention, and raises a new issue After Final.

4. Claim 34 is proposed to depend from claim 33, rather than claim 32, and would therefore recite a new combination of claim limitations not previously considered on the record for the claimed assay device.

5. Additionally, Claim 35 which currently recites the phrase “wherein the first and second gonadotropin-responsive signal producing means produce a signal” is proposed to recite “means” each “produce a signal”, thus requiring two signal producing means,

rather than "a signal" as currently recited in pending claim 35. The proposed claim limitations changes/modifies the scope of the claimed invention, and raises a new issue After Final.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on 7:30-5:00 M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

, Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vgp
April


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